## REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

As indicated in the Office Action Summary, claims 1-8 and 37-38 are currently pending. Claims 1-8 and 37-38 are amended herein. Basis for these amendments may be found throughout the specification and claims as-filed, especially at page 4, lines 14-21, page 4, line 29 to page 5, line 7, page 46, lines 8-19 (treatment of edema, pain, itching, and swelling) and claims 5-6 as-filed, page 10, lines 12-14, page 21, lines 6-10, Example 11 on page 24, Example 13 and Example 18 on page 26 (alkanol as the active ingredient) and page 13, line 36 to page 14, line 2 (alkanol penetrates to layers of skin beneath the stratus corneum). Thus, no prohibited new matter is presented by way of the present Amendment. Applicants reserve the right to file at least one continuation application directed to any subject matter canceled by way of the present Amendment.

### *Objections to the Claims*

Claims 1-8 are objected to for informalities. Specifically, the Office asserts that the phrase "sting or bite is cured" is awkward, as it is the symptoms which are cured rather than the sting/bite itself. Independent claim 1 is amended herein to remove the phrase "sting or bite is cured" and to recite that the effect of the administration of the composition is the reduction and/or inhibition of the symptoms of the bite or sting, *i.e.*, pain, swelling, itching, and edema. Thus, this objection is obviated.

***Rejection under 35 U.S.C. § 112, first paragraph***

Claims 1-8 and 37-38 stand rejected under 35 U.S.C. § 112, first paragraph as purportedly lacking enablement. Specifically, the Office states the while the specification is enabling for specific skin disorders such as itching and swelling, but fails to provide enablement for all possible skin disorders.

In the interest of expediting prosecution, and without acquiescing in the rejection, claims 1-8 are amended herein to recite the following specific skin disorders, as supported in the present specification as-filed: pain, swelling, itching and edema (oedema). Claims 37-38 are amended herein to recite that the effect of the application of the composition is the reduction or inhibition of pain, reduction or inhibition of swelling, reduction or inhibition of itching, reduction or inhibition of edema, or the reduction of infection of skin abrasions or burst blisters, and wherein the effect of the application is a result of the alkanol penetrating to layers of skin below the stratus corneum.

Applicants further submit that these symptoms (localized pain, swelling, itching and edema) are common to bites by insects which sting or suck blood, such as mosquitoes, wasps and bees. Thus, a composition which can, for example, alleviate or inhibit these symptoms in a wasp sting would be able to alleviate these symptoms in a bite/sting from a different insect, such as a bee. Thus, the skilled artisan would be able to practice the claimed methods as amended herein without undue experimentation, based on what is set forth in the specification.

In light of these remarks and amendments, Applicants request that this rejection be withdrawn.

***Rejections under 35 U.S.C. §§ 102 and 103***

**Blackman**

Claims 1-8 stand rejected under 35 U.S.C. § 102 as purportedly anticipated, or alternatively under 35 U.S.C. § 103 as purportedly unpatentable over Blackman et al. (U.S. Patent No. 5,013,545) ("Blackman"). Applicants respectfully traverse.

"[A]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention as arranged in the claims." *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 U.S.P.Q. 253, 256 (Fed. Cir. 1985). Blackman fails to describe or even suggest all of the elements of the rejected claims. The Office asserts that the elements of the present claims are inherently met because the composition of Blackman and that of the present invention are essentially the same, and thus have the same therapeutic effect. Applicants respectfully traverse.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993; *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)

As amended herein, claims 1-8 recite a method comprising administering a composition to the skin of a patient in need to treat itching, pain, swelling and/or edema caused by an insect bite or sting, wherein the active ingredient in the alkanol and the effect of the administration is reduction or inhibition of pain, reduction or

inhibition of swelling, reduction or inhibition of itching, or reduction or inhibition of edema.

Blackman discloses insect bites (see column 4, line 54), but does so in the context of referring to compositions where the active ingredient is an added anti-histamine, anti-inflammatory agent, anti-microbial agent, anti-fungal agent or anaesthetic agent.

Thus, Blackman does not recite the claimed composition or have the same effects. The compositions of the presently claimed invention differ in that the alcohol is the active ingredient, and have the effect of reducing and/or inhibiting pain, edema, swelling and itching. Blackman does not recite each and every element of Applicant's composition or effect of the claimed method. The compositions of Blackman and the present invention are not the same and do not have the same effects.

Further, Applicants submit that the claims are not obvious over Blackman. For a *prima facie* case of obviousness, the following three requirements must be met. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine the reference with another reference. Second, the proposed modification must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. Third, the prior art reference must teach or suggest all the limitations of the claims. The teachings or suggestions as well as the expectation of success must come from the prior art and not from applicant's disclosure. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598

(Fed. Cir. 1988); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991); and *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Applicant respectfully submits that these criteria have not been met in the present Office Action.

First, the references fail to provide motivation to arrive at the present invention or an expectation of success. In column 3, lines 62-65 of Blackman, the reference notes two compositions containing up to 80% alcohol with regard to insect bites. At line 64, Blackman states that compositions containing more than 80% alcohol are less stable and do not contain sufficient water. In contrast, claim 1 of the present invention requires that the amount of alcohol be more than 90% by weight. Thus, Blackman even teaches away from the compositions of the present invention, by stating that such compositions would be unstable due to the high concentrations of alcohol.

Further, Blackman does not associate the compositions with any particular symptoms of the insect bites. In fact, the only effects suggested by Blackman to be associated with reduction or inhibition of insect bite symptoms are a result of inclusion in the compositions of the specific anaesthetic or anti-histamine or anti-inflammatory actives. The present invention is preferably free of such ingredients (*see* specification, page 10, lines 14-18). Therefore, the skilled artisan would not have an expectation of success, as the claimed invention does not contain the above anaesthetic or anti-histamine or anti-inflammatory actives required in Blackman.

Further, Applicants respectfully submit that unexpected results are in fact present with respect to the claimed methods.

It is a well established legal precedent that the presence of an unexpected, advantageous or superior result is evidence of nonobviousness. *See* M.P.E.P. § 716.02(a); *In re Papesch*, 315 F.2d 381, 137 U.S.P.Q. 43 (C.C.P.A. 1963). Along these lines, it is also well established that "a greater than expected result" is evidence of nonobviousness. *See* M.P.E.P. § 716.02(a); *In re Corkill*, 711 F.2d 1496, 226 U.S.P.Q. 1005 (Fed. Cir. 1985).

Previously, alcohol, as used as a solvent vehicle/carrier, caused the concentration and crystallization of medicaments. This problem required larger doses of medicaments than was preferred, in order to ensure a sufficient amount of medicament was available. Thus, the use of alcohol was discouraged.

However, Applicants submit that it has been unexpectedly discovered that compositions having a concentration of alcohol of more than 90% are effective in inhibiting or reducing the specified symptoms of insect bites and stings. Furthermore, this property is shown in four compositions in the specification which contain no other active ingredient other than alcohol to which the reduction of such systems might be due. This clearly shows that the alcohol of the present invention, when utilized at these high concentrations, is therapeutically active. The data also shows that, at lower concentrations, equivalent results are not shown.

**Frost**

Claims 1-4 and 8 stand rejected under 35 U.S.C. § 102 as purportedly anticipated, or alternatively under 35 U.S.C. § 103 as purportedly unpatentable over Frost (U.S. Patent No. 4,923,875) ("Frost"). Applicants note that claims 37-38 are not recited as part of the rejection on page 7, paragraph 5 of the Office Action.

However, as they are discussed on page 8, Applicants assume the Examiner meant to include them in the rejection, and thus address them below.

Applicants respectfully traverse. Frost fails to recite each and every element of the claimed invention. Independent claim 1, as amended herein recites that alcohol is the active ingredient and that the effect of the application of the composition is reduction or inhibition of pain, reduction or inhibition of swelling, reduction or inhibition of itching, or reduction or inhibition of edema. Frost does not recite these elements. In fact, in the composition of Frost, the alcohol is merely a carrier agent, and the active ingredient is nalmefene. Thus, Frost does not recite the composition of the present invention, or the effects of the claimed method.

With regard to claim 37, this claim requires that the alkanol be selected from propanol and mixtures of propanol and ethanol in a particular range. With regard to claim 38, this claim also requires an alcohol other than ethanol ($C_1$, $C_3$ or $C_4$ alkanol) or mixtures with ethanol in a particular ration. Nowhere in Frost is it disclosed or even suggested that ethanol may be replaced with another alcohol. Thus, Frost does not recite each element of the present invention.

Nor is the present invention obvious over Frost. There is no motivation or expectation of success with regard to Frost, as Frost contains an active ingredient, malmefene, and merely uses the alcohol as a carrier. As noted above, Frost does not recite replacing the ethanol with any other alkanol, let alone with propanol. There is thus no obvious step in providing a different alcohol base from that of Frost example 4.

The Office further argues that Frost discloses mixtures of alcohols. However, the mixture of Frost is of the commonly available alcohol, ethanol, plus propylene

glycol. There is no suggestion by Frost that an amount more than a small proportion, for instance no more than 10%, of another glycol could be included. There is no suggestion that any alkanol other than ethanol should be used to form the base of the composition. There is certainly no suggestion that propanol could be utilized, as required by claim 37. Nor is there any suggestion to use one of the other alkanols mentioned in claim 38 in place of a substantial proportion of ethanol. In light of the above, Applicants request that this rejection be withdrawn.

**Marks**

Claims 37-38 stand rejected under 35 U.S.C. § 102 as purportedly anticipated, or alternatively under 35 U.S.C. § 103 as purportedly unpatentable over Marks(U.S. Patent No. 4,247,547) ("Marks"). Applicants traverse.

Marks fails to recite each element of claims 37 and 38. Claims 37 and 38 are directed to methods of treatment wherein the effect of the application of the composition is reduction or inhibition of pain, reduction or inhibition of swelling, reduction or inhibition of itching, or reduction or inhibition of edema, or the reduction of infection of skin abrasions or burst blisters; and wherein the effect of the application is a result of the alkanol penetrating to layers of skin below the stratus corneum. Thus, with claims 37-38, the effect of the alkanol active is due to the penetration of the composition below the stratum correum skin layer.

In contrast, Marks discloses tretinoin as the active, optionally in combination with other therapeutically effective compounds. As with the previous references, alcohol is used merely as a carrier and not to have any therapeutic effect.

As a result, Applicants further submit that the skilled artisan would not have an expectation of success or motivation to modify Marks. Marks uses alcohol merely as the carrier and not as the active. Instead, Marks discloses another active ingredient, to which the effects are attributed. In contrast, the active ingredient of the present invention is the alkanol, and the effects are due to the alkanol active, i.e., the ability of the concentration of alkanol to penetrate below the stratum correum skin layer.

In light of the above, Applicants respectfully request that the rejections under 35 U.S.C. §§ 102 and 103 be withdrawn.

***Rejection under the Judicially Created Doctrine of Obviousness-type Double Patenting***

Claims 1-8 and 37-38 stand rejected under the judicially created doctrine of obviousness type double patenting as purportedly unpatentable over U.S. Patent No. 5,981,605. Applicants traverse.

Claims 1 to 8 of the present invention are directed to treatment of particular symptoms of insect bites and stings, *i.e.,* itching, swelling, edema and pain. Claims 37 and 38 require particular alkanols other than ethanol and/or mixtures in particular ratios of such alcohols with ethanol. There are several advantages and certainly significant differences with regard to these specific alkanols.

In contrast, the claims of U.S. Patent No. 5,981,605 are directed to a method of treatment of infected skin by topical application to the infected area of skin of a gel form pharmaceutical composition comprising a polymer gelling agent, more than 90% by weight of at least one $C_{1-4}$ alkanol, and less than 10% by weight water based on the total weight of composition, wherein said alkanol is substantially the only

active agent in said composition and said composition is free of any additional ingredients which would substantially reduce gel stability.

Applicants request that this rejection be withdrawn.

## CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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